

REMARKS

Status of Claims

Claims 1-32 are pending. Applicants note that the Office Action Summary only indicates claims 1-31 as pending. Applicants assume that this is a typographical error and that the “31” should be a “32.”

Restriction Requirement under 35 U.S.C. §§ 121 and 372

The Office requires restriction under 35 U.S.C. §§ 121 and 372 between two groups of claims:

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| Group I | Claims 1-15 and 26-31, drawn to “a permselective asymmetric hollow fiber membrane,” “method of performing hemodiafiltration,” “method of performing hemodialysis,” and “method of performing hemofiltration” using the apparatus of claim 1; and |
| Group II | Claims 16-25, drawn to “a process for the preparation of a membrane.” |

Applicants assume that claim 32 (a process claim) is part of Group II.

According to the Office, the inventions of Groups I and II do not form a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Office Action at 2. The Office argues that U.S. Patent Publication No. 2004/0060866 (“*Radunsky*”) discloses a technical feature that is “similar” to the common technical feature of Groups I and II.

Applicants respectfully disagree and traverse the restriction requirement for the following reasons. *Radunsky* discloses a membrane used for hemofiltration that results in removal of albumin from the patient’s blood. See, e.g., *Radunsky* at ¶¶ 17-19 and 32. In order to maintain an adequate level of albumin, *Radunsky* administers a replacement fluid containing albumin to the patient. See, e.g., *id* at Abstract, ¶ 55. Since albumin

has a molecular weight of about 69,000 Dalton, *Radunsky's* membrane therefore allows passage of molecules from blood having a molecular weight of at least 69,000 Dalton. This is a significantly higher molecular weight than 45,000 Daltons. See also *Radunsky* at ¶ 52 (indicating that “the nominal molecular weight cutoff to provide adequate sieving of target receptor molecules, target complex molecules, and target molecules, is expected to be approximately 150,000 to 500,000 Dalton”).

The instantly claimed invention, however, “allows passage of molecules having a molecular weight of up to 45,000 Daltons in presence of whole blood,” and, therefore, albumin is not removed from the blood in significant amounts. See, e.g., claim 1 (emphasis added); specification at 5, lines 7-11. Thus, *Radunsky* does not destroy the unity of invention of the claimed invention. Accordingly, Group I and Group II relate to the same inventive concept because they share the special technical feature of a permselective asymmetric hollow fibre membrane that allows passage of molecules having a molecular weight of up to 45,000 Daltons in presence of whole blood.

Moreover, Applicants respectfully remind the Office of the rejoinder procedure under M.P.E.P. § 821.04(b), which calls for a withdrawal of the restriction requirement and examination of the process claims once the product claims have been allowed.

Accordingly, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn, and all pending claims be examined in this application.

In order to be fully responsive, however, Applicants elect Group I (i.e. claims 1-15 and 26-31) for further consideration in case the restriction requirement is maintained.

Conclusion

In view of the foregoing remarks, Applicants respectfully request reconsideration and examination of this application and the timely allowance of the pending claims. If the Examiner believes a telephone conference would be useful in resolving any outstanding issues, the Examiner is invited to call the undersigned at (202) 408-4123.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: February 20, 2009

By: 

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